Complete Summary

GUIDELINE TITLE

ACR Appropriateness Criteria[™] for work-up of the solitary pulmonary nodule (SPN).

BIBLIOGRAPHIC SOURCE(S)

Henschke CI, Yankelevitz D, Westcott J, Davis SD, Fleishon H, Gefter WB, McLoud TC, Pugatch RD, Sostman HD, Tocino I, White CS, Bode FR, Swensen SJ. Work-up of the solitary pulmonary nodule. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun; 215 (Suppl): 607-9. [19 references]

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Solitary pulmonary nodule

GUIDELINE CATEGORY

Diagnosis

CLINICAL SPECIALTY

Oncology Pulmonary Medicine Radiology

INTENDED USERS

Physicians

GUI DELI NE OBJECTI VE(S)

To evaluate the appropriateness of radiologic exam procedures for imaging and treatment decisions in the work-up of the solitary pulmonary nodule (SPN)

TARGET POPULATION

Patients with a solitary pulmonary nodule (SPN)

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. High resolution computed tomography
- 2. Contrast-enhanced computed tomography
- 3. Fine needle aspiration biopsy (computed tomography or fluoroscopy guided)
- 4. Positron emission tomography scan
- 5. Bronchoscopy
- 6. Thoracoscopy
- 7. Surgical resection (for diagnosis)

MAJOR OUTCOMES CONSIDERED

Utility of radiologic exam procedures in differential diagnosis

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of recent peer-reviewed medical journals, primarily using the National Library of Medicine´s MEDLINE database. The developer identified and collected the major applicable articles.

NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Delphi Method)
Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed to reach agreement in the formulation of the Appropriateness Criteria. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty (80) percent agreement is considered a consensus. If consensus cannot be reached by this method, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria and the Chair of the ACR Board of Chancellors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria™

<u>Clinical Condition</u>: Solitary Pulmonary Nodule, Noncalcified.

<u>Variant 1</u>: Nodule \geq 1 cm, low clinical suspicion for cancer.

Radiologic Exam Procedure	Appropriateness Rating	Comments
High-resolution computed tomography	8	
Fine needle aspiration	8	
Watchful waiting with computed tomography follow-up	8	
Contrast-enhanced computed tomography	6	
Positron emission tomography scan	6	If available. Appropriateness depends on results of other tests such as high-resolution computed tomography, contrast enhanced computed tomography, and results, availability and local expertise in the performance of needle biopsy.
Bronchoscopy	4	
Thoracoscopy	3	Not as the preferred initial approach.
Surgical resection (for diagnosis)	2	

<u>Appropriateness Criteria Scale</u>

123456789

1=Least appropriate 9=Most appropriate

<u>Variant 2</u>: Nodule \geq 1 cm, moderate to high clinical suspicion for cancer.

Radiologic Exam Procedure	Appropriateness Rating	Comments
High-resolution computed tomography	8	
Contrast-enhanced computed tomography	8	
Fine needle aspiration	8	
Positron emission tomography scan	6	If available. Appropriateness depends on results of other tests such as high-resolution computed tomography, contrast enhanced computed tomography, and results, availability and local expertise in the performance of needle biopsy.
Surgical resection (for diagnosis)	5	Depends on institution, accuracy and results of needle biopsy, availability of positron emission tomography, etc.
Bronchoscopy	4	
Thoracoscopy	3	Not as the preferred initial approach.
Watchful waiting with computed tomography follow-up	2	

Appropriateness Criteria Scale

123456789

1=Least appropriate 9=Most appropriate

<u>Variant 3</u>: Nodule \leq 1 cm, low clinical suspicion for cancer.

Radiologic Exam Procedure	Appropriateness Rating	Comments
High-resolution computed tomography	8	
Watchful waiting with computed tomography follow-up	8	
Contrast-enhanced computed tomography	4	
Positron emission tomography scan	4	If available. Appropriateness depends on results of other tests such as high-resolution computed tomography, contrast enhanced computed tomography, and results, availability and local expertise in the performance of needle biopsy.
Fine needle aspiration	4	Depends on operator experience and size and accessibility of nodule.
Bronchoscopy	2	
Thoracoscopy	2	
Surgical resection (for diagnosis)	2	

Appropriateness Criteria Scale

123456789

1=Least appropriate 9=Most appropriate

<u>Variant 4</u>: Nodule \leq 1 cm, moderate to high clinical suspicion for cancer.

Radiologic Exam Procedure	Appropriateness Rating	Comments
High-resolution computed tomography	8	
Fine needle aspiration	8	
Positron emission tomography	6	If available. Appropriateness

scan		depends on results of other tests such as high-resolution computed tomography, contrast enhanced computed tomography, and results, availability and local expertise in the performance of needle biopsy.
Thoracoscopy	5	If needle biopsy is not available, not technically feasible, or is nondiagnostic.
Contrast-enhanced computed tomography	4	Limited data available.
Surgical resection (for diagnosis)	4	
Watchful waiting with computed tomography follow-up	3	To be considered only when nodules are very small and biopsy is not technically feasible, and in patients who are poor surgical risks.
Bronchoscopy	2	

Appropriateness Criteria Scale

123456789

1=Least appropriate 9=Most appropriate

In view of the variety of diagnostic tests available and the variable accuracy of the different diagnostic techniques, no single algorithm for work-up is generally accepted. It has been found to vary from institution to institution. This is probably appropriate given the varying prevalence of disease in different parts of the country and the varying skill levels and availability of equipment.

CLINICAL ALGORITHM(S)

Algorithms were not developed from criteria guidelines.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate selection of radiologic exam procedures in the work-up of the solitary pulmonary nodule.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination. ACR appropriateness criteria are not designed as a guide for third-party reimbursement.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1995 Sep (revised 2000)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria $^{\text{TM}}$.

GUI DELI NE COMMITTEE

ACR Appropriateness Criteria™ Committee, Expert Panel on Thoracic Imaging

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: David Yankelevitz, MD; Claudia Henschke, MD, PhD; Jack Westcott, MD; Sheila D. Davis, MD; Howard Fleishon, MD; Warren B. Gefter, MD; Theresa C. McLoud, MD; Robert D. Pugatch, MD; Henry Dirk Sostman, MD; Charles S. White, MD; Frederick R. Bode, MD; Stephen Swensen, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline. It is a revision of a previously issued version (ACR Appropriateness Criteria[™] for work-up of the solitary pulmonary nodule (SPN). Reston [VA]: American College of Radiology [ACR]; 1995, 5 p.).

The ACR Appropriateness Criteria[™] are reviewed after five years, if not sooner, depending upon introduction of new and highly significant scientific evidence. The next review date for this topic is 2004.

GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>American College of Radiology (ACR) Web</u> site.

Print copies: Available from ACR, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on March 25, 1999. The information was verified by the guideline developer on September 9, 1999. The summary was updated on February 12, 2002. The information was verified again by the guideline developer on March 25, 2002.

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